REMARKS

The Examiner has required Applicants under 35 U.S.C. § 121 to elect one of the following inventions:

I. Claims 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 99, 101, 102, 104 and 112, drawn to a method of treatment using NKT cells to promote inflammation, classified in Class 424, subclass 93.1.

II. Claims 6, 7, 8, 9, 10, 11. 12, 13, 15, 19, 24, 32, 146, 147, 148, 149, 150 and 151, drawn to a method of treatment using NKT cells as an anti-inflammatory, classified in Class 424, subclass 93.21.

III. Claims 16, 17, 18, 20, 23, 96, 97, 98, 100 and 103, drawn to a method of treatment using oral tolerization to elicit up or down regulation of the immune system, classified in Class 424, subclass 184.1.

V. Claims 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62 and 63, drawn to ex-vivo educated NKT cells capable of acting as anti-inflammatory agents, classified in Class 424, subclass 93.7.

VI. Claims 66, 67, 68, 69, 70, 71, 72, 155, 156, 157, 158, drawn to a therapeutic composition comprising an antibody that recognizes NKT cells, classified in Class 424, subclass 130.1.

VIII. Claims 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 152, 153 and 154, drawn to ex-vivo educated NKT cells capable of acting as pro-inflammatory agents, classified in Class 424, subclass 93.71.

IX. Claim 5, drawn to a method of treatment involving depletion of NKT cells as an anti-inflammatory, classified in Class 424, subclass 140.1.

X. Claim 85, drawn to a method of treatment involving depletion of NKT cells to promote inflammation, classified in Class 424, subclass 154.1.

In addition, the Examiner states that if Applicants elect any of Groups I, II, III, IX, or X, they are required to elect one specific immune-related or immune-mediated disorder to be treated.

Also, if Applicants elect either Group I or II, they are required to elect one specific set of culture conditions for the ex vivo education of NKT cells.

ELECTION

Applicants respectfully request withdrawal of the restriction requirements and ask that all claims be prosecuted in the same patent application. In the event that the restriction requirement is not withdrawn and solely in order to comply with 37 C.F.R. § 1.143, Applicants hereby provisionally elect Group II, directed to claims 6, 7, 8, 9, 10, 11, 12, 13, 15, 19, 24, 32, 146, 147, 148, 149, 150 and 151, as drawn to a method of treatment using NKT cells as an anti-inflammatory, with traverse.

Applicants hereby provisionally elect Autoimmune Liver Disease as the specific immune-related or immune-mediated disorder, with traverse. As the Examiner requested, Applicants identify the claims encompassing this elected species as claims 6, 7, 8, 9, 10, 11, 12, 13, 15, 19, 24, 32, 146, 147, 148, 149, 150, 151, 165 and 166.

Applicants also hereby provisionally elect "antigens or epitopes" and "allogenic antigens obtained from donors suffering from said immune-related or immune-mediated disease", directed to claims 7, 8, 9, 32, 147, 149, 151, 165 and 166, with traverse.

Applicants provisionally elect "liver-associated cell" and "Kupffer cells", directed to claims 7, 8, 10, 32, 147, 149, 151, 165 and 166, with traverse.

Finally, Applicants provisionally elect "cytokine or adhesion molecule" and "IL4", directed to claims 7, 8, 11, 32, 147, 149, 151, 165 and 166, with traverse.

Applicants reserve the right to file divisional application(s) directed to non-elected subject matter and reserve the right to petition the restriction requirement. Applicants also acknowledge that, upon allowance of a generic claim, they will be entitled to consideration of additional claims which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141.

TRAVERSAL

Applicants respectfully traverse the Examiner's restriction requirements and request withdrawal of the requirement for the following reasons. Restriction between inventions is only proper when a search burden exists for the Examiner to search all of the inventions claimed. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions (see MPEP § 803.01). In the instant case, groups I, II, IX and X all encompass claims that : 1) seek to modulate the Th1/Th2 cell balance; 2) manipulate the NKT cell population in some way to modulate the Th1/Th2 cell balance; and 3) treat an immune-related or immune-mediated disorder or disease in a mammalian subject. As such, since these four groups are related and overlap, they should not be categorized as different inventions since a search of their subject matter would not constitute a serious search burden for the Examiner. Additionally, in Groups V and VIII, all the claims disclose: 1) compositions for the treatment of an immune-related or immune-mediated disorder or disease in a mammalian subject; 2) compositions comprising NKT cells; and 3) NKT cells which modulate the Th1/Th2 cell balance. Since these two groups are related and overlap, they also should not be categorized as separate inventions since a search of their subject matter would not constitute a serious search burden for the Examiner.

The Examiner stated the following:

> Groups V/VI and II/IX, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, inflammatory immune diseases can be treated with agents other than NKT cells or depleting anti-NKT antibodies, for example, with corticosteroids.

Applicants respectfully disagree. The inventions are not distinct because the process for using the product as claimed can not be practiced with another materially different process of using that product. Treatment of inflammatory immune diseases with corticosteroids would not achieve the desired results of the present invention. The result would be a general immunosuppression and not a specific immunosuppression (as the present invention achieves). This general suppression leads to undesirable side effect, as seen in numerous prior art sources. Additionally, since conditions frequently become steroid-resistant, corticosteroids are not effective agents for treatment.

The Examiner also stated:

> Groups VIII/VI and I/X and are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, immune diseases requiring more inflammation can be treated with agents other than NKT cells or depleting anti-NKT antibodies, for example with an adjuvant.

Applicants respectfully disagree. These inventions are not distinct because the process for using the product as claimed can not be practiced with another materially different process of using that product. Immune diseases requiring increased inflammation are not best treated with an adjuvant, which is a general inflammatory booster. As such, it may increase inflammatory responses that are not the target of the treatment, in addition to inflammatory responses that are considered to be reliable.

Regarding the species election for the specific immune-related or immune-mediated disorder to be treated, Applicants traverse on the ground that the species are not patentably distinct. All of these diseases or disorders are obvious variants of each other – they can all be treated by shifting the Th1/Th2 cell balance towards Th2, an anti-inflammatory response. Furthermore, treatment of all of these disorders or disease results in an increase of the CD 4^{+}

$IL4^+$ $IL10^+/CD4^+$ IFNγ ratio.

With regard to the species election regarding the one specific set of culture conditions, these molecules (antigens or epitopes, liver- associated cell and cytokines or adhesion molecules) are not patentably distinct. Specifically, all of the listed antigens or epitopes contribute to the development of an immune-related or immune-mediated disorder or disease. It is the association of the antigen with a particular disorder or disease that gives a common utility to the antigen. All of the liver associated cells share the commonality that they are all found in the liver, or otherwise, that all of the cells actually constitute the liver organ. The listed cytokines are all proteins that are excreted by cells known to effect the growth or activity of other cells by binding to their appropriate receptor on the cell. There would be no examination and search burden for these patentably distinct species since different searches would not be required – "antigens or epitopes", "liver-associated cells" and "cytokines or adhesion" molecules each comprise well-established groups in the relevant art that are easily searchable.

Moreover, Applicants respectfully submit that the groups and species have not acquired a separate status in the art for examination purposes. In particular, the Examiner has failed to establish separate states in the art by citing patents which are evidence of such separate status, or showing separate field of search.

Accordingly, the restriction requirements will serve no purpose other that to unfairly and improperly require Applicants to pay duplicate PTO fees to obtain patent protection for their invention.

CONCLUSION

Applicants maintain that the restriction requirements are improper and that all pending claims should be examined for patentability. If the Examiner believes that the prosecution might be advanced by discussing the Application with the Applicants' attorney, he should kindly contact the undersigned.

No fee is believed due in connection with this Amendment. If any fee or fees are due however, the United States patent and Trademark Office is hereby authorized to charge the amount of any such fee to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Early and favorable action is respectfully requested.

Respectfully submitted,

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